WHALETEQ

Common Mode Rejection Ratio Tester
(CMRR 2.0)

User Manual
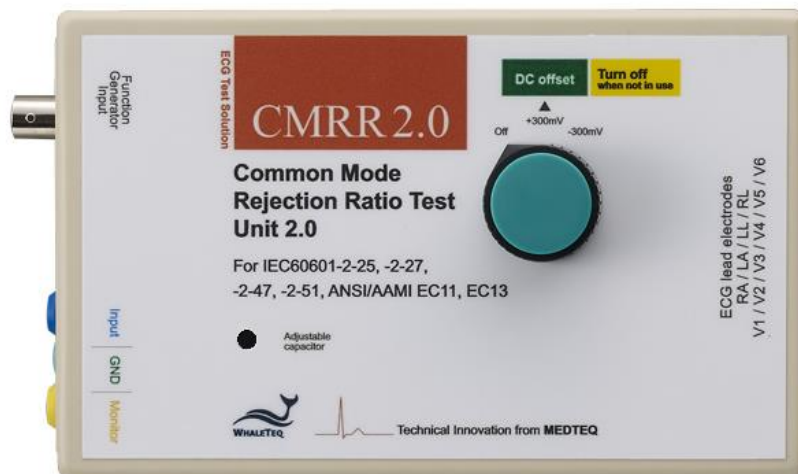
(Revision 2015-08-14)

Contents

1   Introduction

WhaleTeq's main focus is on tests in ECG standards is the Single Channel and Multichannel ECG test systems. However, these systems do not cover *common mode rejection ratio* due to the nature of test (double box construction, noise free environment). To meet this need, WhaleTeq has developed a CMRR test box.

The box is uses the double shield construction according to various IEC standards (IEC 60601-2-25, IEC 60601-2-27, IEC 60601-2-47, IEC 60601-2-51), and includes the following special features:

-   Switching is eliminated by having the imbalance impedance and dc offset available on a special terminal on the CMRR   ECG Breakout box. Although the diagram shown in standards has all the switches open, for the actual test, only one switch is required to be open at a time. Rather than switching in the imbalance, the user simply changes the external electrode connections to the imbalance terminal. Elimination of these switches greatly simplifies the design of the CMRR box.

-   The box includes a step up transformer to allow a normal signal generator to be used. The tests in IEC 60601-2-25: 2011, IEC 60601-2-27 and IEC 60601-2-51 require a 20Vrms supply, and most function generators are limited to 7Vrms. This feature can be bypassed if desired by connecting directly to the blue (input monitor) 4mm socket.

-   The box includes a 1000:1 (50MΩ:50kΩ) voltage divider to allow monitoring of the applied voltage. The standard requires that the unloaded voltage is adjusted to 10Vrms, however, the source impedance is sufficiently high that it cannot be measured by normal meters. A 1000:1 divider, constructed of 50MΩ:50kΩ and is permanently connected has been found to be the best compromise between accuracy, circuit loading, noise and input impedance of typical multimeters. Using this feature the adjusted voltage should be 10mVrms (or 1/1000 of the target voltage).

-   The box includes a precision, stable ±300mV source as used in other WhaleTeq equipment

2   Description

2.1   CMRR Box

The CMRR box internal construction as below, the only features not shown is the internal screen (internal box), which is provided around the circuit floating at 10Vrms as shown by the blue shading below:
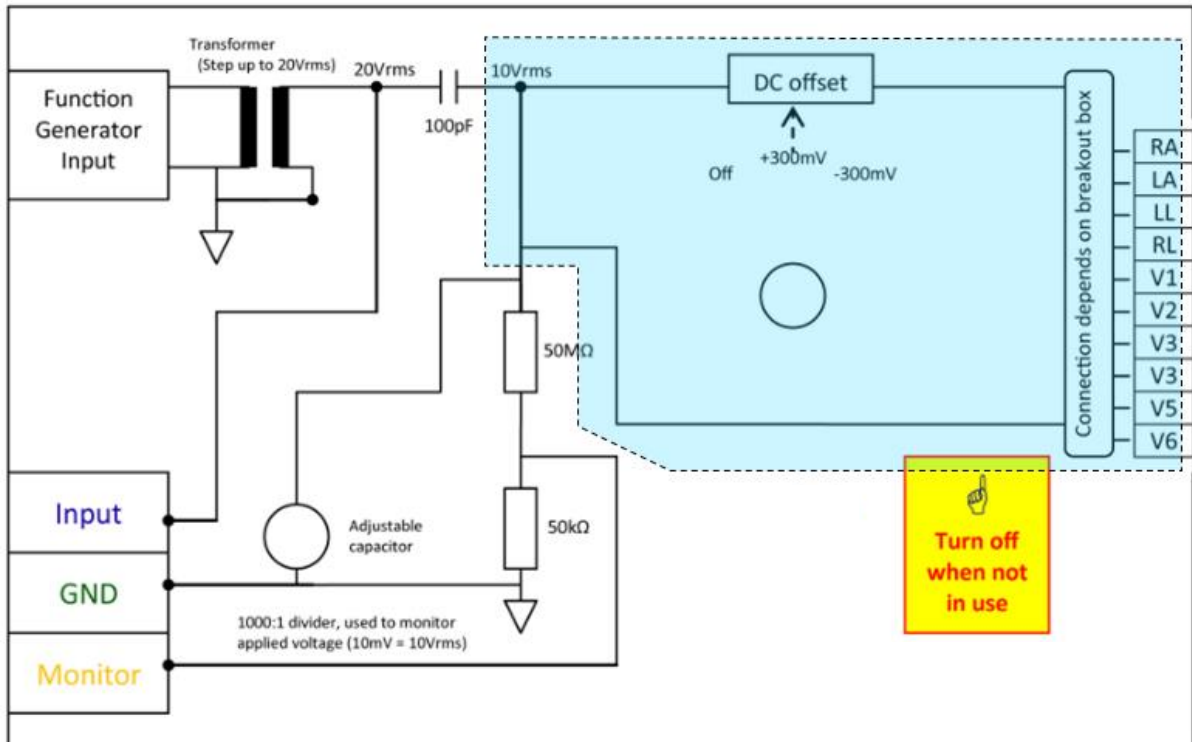
For connecting the CMRR Box to test the ECG device, use the "ECG breakout box" provided, as explained on the following page.

Alternately the ECG device under test can be directly connected to CMRR Box using a male D15 connector. The pin outs are:

1 - RA   4 - RL   7 - V3   10 - V6
2 - LA   5 - V1   8 - V4   11 - CMRR inner box
3 - LL   6 - V2   9 - V5   12 - DC offset (no impedance)
                           13 - DC offset (impedance)

The imbalance can be determined by external connections, simulating the ECG breakout boxes on the following page.

2.2   ECG Breakout Boxes

The WhaleTeq CMRR 2.0 is supplied with two breakout box to suit different standards.

IEC 60601-2-25: 2011 (formerly IEC 60601-2-51), IEC 60601-2-47: 2012 and IEC 60601-2-27 requires 9 leads (RA/RL/LL/V1 to V6) to be shorted to inner box with only RL/N and Imbalance (with DC) having the impedance of 51kΩ /47nF. To implement this, a special breakout box is used which shorts 9 terminals to the inner shield, except RL/N and Imbalance with DC terminal:
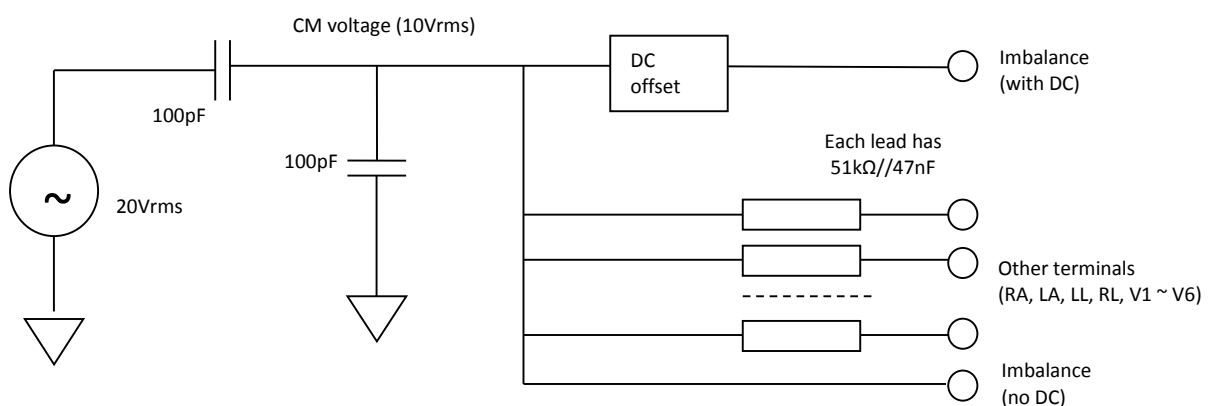
The effective circuit is:
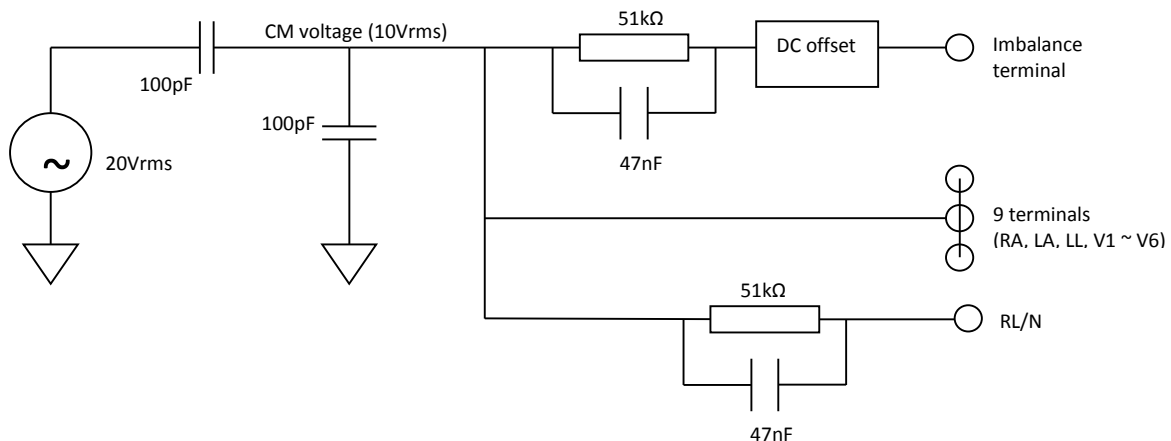
The test circuit in IEC 60601-2-47: 2001 and ANSI/AAMI EC 13 is the same except that all lead electrodes have the 51k/47nF, except one which is directly connected to the inner shield:
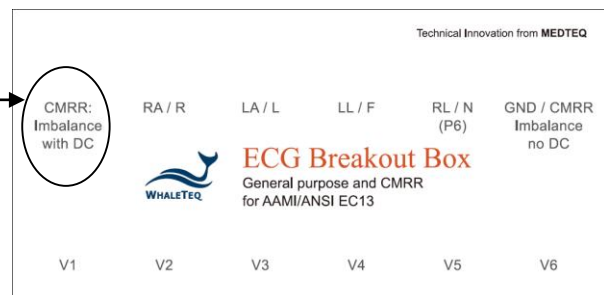
This has the effective circuit:

3 Set up

3.1 Environment, noise reduction

A noise free environment is necessary for testing ECG equipment. This can be achieved relatively easily by using a metal bench or metal sheet underneath the ECG device under test, the WhaleTeq CMRR test unit, and also connecting together the ground as shown:

Metal bench, metal sheet or foil
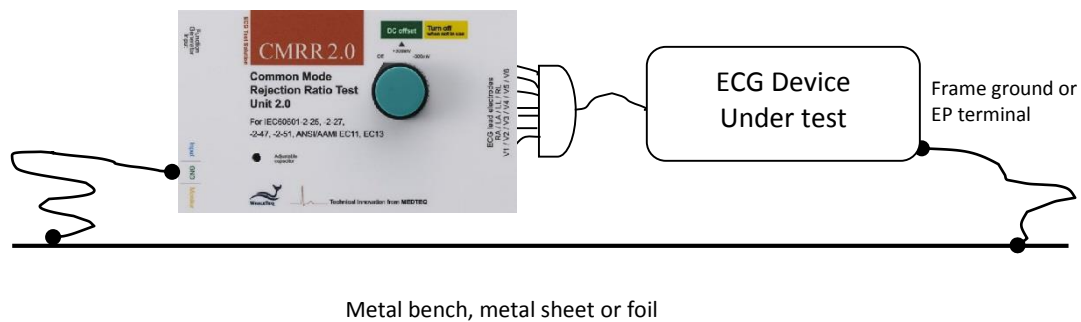
With this set up, turn the ECG device under test to maximum sensitivity, turn off the ac filters (if possible) and with the function generator supply OFF, confirm that the noise indication is <1mm (0.1mVpp).

4   Calibration

As per ISO/IEC 17025, the system should be calibrated either before use or on a periodic basis. For the CMRR test some compromises must be made due to the nature o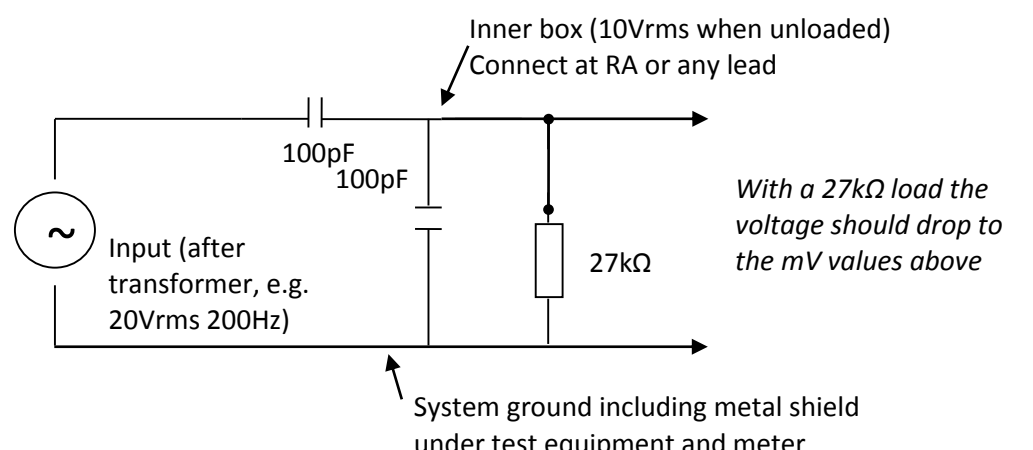f the circuit. The following process for calibration is recommended (Note: as tests are infrequent, and the calibration method is specialized, it is recommended to calibrate before use).

Parameter	Nominal value	Tolerance	Method
Applied voltage	20Vrms*	±1%	Can be measured between the "Input" and "GND" terminals using a calibrated meter
Source capacitance	100pF	±5%	In general traceability for capacitance is not easy to obtain. An alternate method involves using the 27kΩ resistor also used for verifying the WhaleTeq Single channel system. With the 27kΩ connected between RA and ground, the voltage should drop to: At 20Vrms, 50Hz: 16.97mVrms±10% At 20Vrms, 60Hz: 20.35mVrms±10% At 20Vrms, 200Hz: 67.9mVrms±10% A test supply of 200Hz is recommended to minimize the influence of noise. If available, a low pass filter on the meter should be used to eliminate noise from high frequency sources.

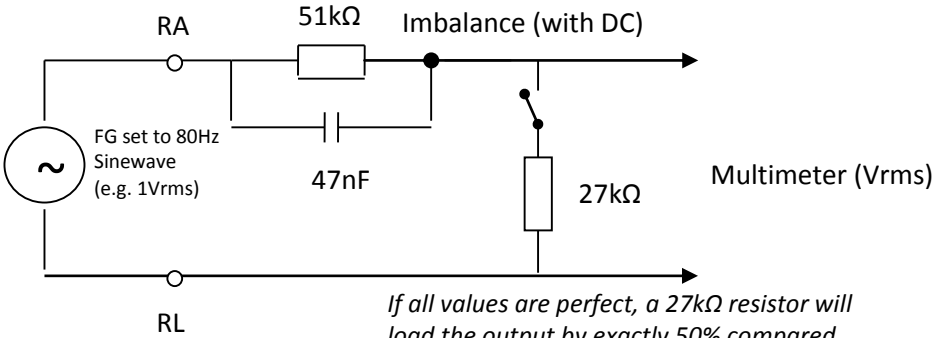Inner box (10Vrms when unloaded)
Connect at RA or any lead

100pF
100pF

Input (after transformer, e.g. 20Vrms 200Hz)

27kΩ

With a 27kΩ load the voltage should drop to the mV values above

System ground including metal shield under test equipment and meter

Shield voltage	10Vrms	±15%	This can be measured indirectly using the internal 50MΩ:50kΩ divider. A measured voltage of 10mVrms between the "Monitor" and "GND" terminals is equivalent to 10Vrms. To eliminate noise, a battery operated meter with short leads, located on the GND shield should be used. The noise without any voltage applied should ideally be <0.5mVrms, but not more than 1mVrms. If the meter has a low pass filter function this should be used to eliminate noise at higher frequencies (e.g 1kHz +) As per the standard, this voltage should be adjusted to 10Vrms without the ECG device under test connected. If the ECG breakout box is used, this should be connected prior to adjustment. The "adjustment capacitor" can be adjusted using a small screw driver. The adjustment uses a half turn capacitor (5-30pF, or in later units 6-50pF) *without an end stop,* meaning that if it is continued in one direction the voltage will start to increase again. Use small incremental adjustments and allow the voltage to stabilize after adjustment. It is recommended to use a metal screw driver for good mechanical contact, with an insulated handle (e.g. with 3-4 layers of electrical tape if required). Using this the voltage is adjusted to be around 3-5% lower than required. After removing the screwdriver the voltage will increase ~3-5%. Using the component tolerances given in the standard, an acceptable range is ±15% (8.5mV ~ 11.5mV). However, it is recommended to adjust to within 9.5 ~ 10.5mV (±5%) to ensure repeatability of the test.
Impedance imbalance, R	51kΩ	±1%	This can be measured between Imbalance (with DC) terminal and any other lead electrode (with the DC offset off).

Impedance imbalance, C	47nF	±5%	This can be measured between Imbalance (with DC) terminal and any other lead (with DC offset set to off). Measurement of capacitance in circuit can be done provided that the meter's measurement frequency is 1kHz or higher, to minimize the influence of the 51kΩ parallel resistor. However, traceability for capacitance is generally impractical. An alternate method is used which is based on the loaded output – see circuit below. For this circuit, an 80Hz sine wave source having a source impedance of 51kΩ/47nF will be loaded by 50% (0.500) by a 27kΩ resistor. A capacitance error of ±10% corresponds to variation of 47.8% and 52.2% loading by a 27kΩ resistor.

If all values are perfect, a 27kΩ resistor will load the output by exactly 50% compared to the unloaded value when using 80Hz

DC offset	±300mV	±1%	This can be measured between Imbalance (with DC) terminal and any other lead with DC set to +300mV and/or -300mV. Note that due to the series resistance of 51kΩ, the measured value will read 0.5% low if a typical 10MΩ input impedance meter is used. Therefore the expected reading is ±298.5mV. This offset is sourced by a small internal battery which is calculated to provide over 24hrs of continuous use, and should exceed the lifetime of the equipment.

5   Principle of the CMRR test

5.1   Common mode rejection ratio explained

A perfect device measuring a *differential voltage* should not respond to the level of *common mode voltage* which appears at both inputs. For example, a multimeter where the plus terminal is +100.017V and the minus terminal is +100.001V should theoretically indicate measured voltage of 16mV.

In practice, due to slight differences in resistances used in differential amplifiers, some of the common mode voltage will come through as an error. The *common mode rejection ratio* or CMRR indicates the ability of the equipment to reject these common mode voltages.

A scale of dB is normally used as the ratio can range from as low as 100 up to 100,000 (40dB to 100dB). A CMRR of 60dB indicates a ratio of 1000, and means that common mode voltages will be reduce by a factor of 1000. In the example given, equipment with a CMRR of 60dB would have the common voltage (+100V) reduced to 10mV, still a significant error relative to the differential voltage of 16mV. In practice the common mode voltage is usually not more than 10 times the differential voltage, so a CMRR of 60dB would only result in a 0.1% error.

The most common source of common mode noise is mains voltages, i.e. 50/60Hz. Thus, CMRR in meters is usually specified at these frequencies. But it is important to note that CMRR varies with frequency.

Common mode rejection also varies with the impedance of the source, or more specifically the impedance *imbalance*, as the imbalance also upsets the measurement circuit. CMRR for multimeters is typically specified with a 1kΩ imbalance.

5.2   Common mode rejection in ECG equipment

ECG equipment can be subjected to a fairly high common mode voltage from mains noise (50/60Hz), and can have a much higher impedance imbalance. The test in the standard simulates 10Vrms, with an imbalance of 51kΩ//47nF, and allows an indication equivalent to 0.35mVrms (1mVpp). This requires ECG equipment to have a relatively large CMRR of 89dB[1]. In practice, ECG equipment handles this large CMRR in five ways:

- Intentional capacitance between the patient circuit and earth, small enough not to cause leakage current problems, but large enough to load the source, and reduce the voltage by 50% or more. This is the reason for the 100pF in the test circuit.
- "Right leg drive": this is similar to noise reducing headphones, where the "noise" is sensed on measurement leads (e.g. RA, LA, LL), inverted and then returned via the RL/N lead electrode. Also referred to a noise cancellation.
- Patient isolation barrier, which reduces the impact of the common mode voltage
- High CMRR input op amps, to handle the residual common mode voltage
- Finally, filtering can be used to remove residual common mode mains noise

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[1] This value can be calculated from $20 \log_{10} (10V / 0.35mV)$

While filtering is often used in practice, it is reasonable to confirm that the hardware features can provide sufficient CMRR without filtering. This ensures that distortion of the signal will not occur. For this reason, mains notch filtering (ac filter) must be turned off for the test even if it requires special software to do so. This is one point where the IEC standard differs from US and other standards.

5.3   Test equipment

Refer to the standard for the test circuit.

From a testing point of view the series 100pF introduces significant complications, as it represents a very high impedance of about 30MΩ at 50/60Hz. This means that attempts to measure the applied voltage (10Vrms) with a normal multimeter will fail, because the meter has around 10MΩ input impedance. It is possible to use 1000:1 HV probe with an oscilloscope (100MΩ/3pF), but noise and other errors can be large. Even 100MΩ/3pF will load the circuit, so the voltage will change (increase) by about 5% after the HV probe is removed, which should be accounted for if such probes are used.

WhaleTeq's equipment incorporates a 50MΩ/50kΩ 1000:1 divider to allow monitoring by a typical digital multimeter (10mVrms = 10Vrms). The value of 50MΩ has been chosen as the best compromise between loading the circuit, noise and accuracy. As the divider remains in circuit it at all times the unloaded applied voltage (without the ECG connected) can be considered accurate. However, the 50MΩ can slightly change the loaded voltage once the ECG is connected (because it is resistive, not capacitive). The error introduced will vary based on ECG's capacitance to ground, but simulations indicate this error is small and in the very worst case will still be less than 3%.

The 100pF also creates a problem with the position of the patient cable. If the cable is allowed to sit on an earthed plane, the stray capacitance can be enough to provide additional loading and reduce the actual common mode voltage. This stray capacitance is highly variable and thus can impact the test. For conservative tests, the cable should be supported off the earth plane, but remain above the earth plane in order to minimize noise.

For IEC 60601-2-25: 2011, IEC 60601-2-27 and IEC 60601-2-51, the test requires a 20Vrms source. This can be sourced from the mains supply but for those wishing to test at various frequencies and have good control over the applied voltage, use of a function generator is more convenient. A function generator is usually limited to 7.1Vrms (20Vpp). To assist with this, WhaleTeq's equipment has a small transformer built into the equipment which allows the voltage to be stepped up to 20Vrms. The applied voltage can then verified at the "Input" and "GND" terminals.

Common mode rejection is also dependent on impedance imbalance. For this reason, the test also introduces an imbalance of 51kΩ//47nF in one lead only. Experience from tests indicates that without this imbalance, there is usually no visible indication on the ECG, but with the imbalance readings typically range between 3-7mm (0.3 ~ 0.7mVpp). This suggests that the value of imbalance impedance is critical for the tests. Although the diagram in the standard shows all switches open, for the purpose of the test, all switches should be closed except the lead being tested. WhaleTeq's device takes advantage of this to eliminate all switches.

IEC 60601-2-27 requires a dc offset of ±300mV, while IEC 60601-2-25: 2011 and IEC 60601-2-51 consider that other tests have proved the ability to handle a dc offset. The dc offset is sourced by an internal battery. The lifetime of this battery is estimated to be at least 50 hrs, which should far exceed the lifetime of the equipment if the switch is returned to the "Off" position after use. If the
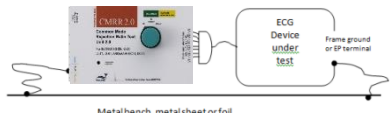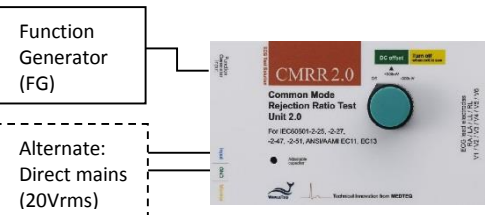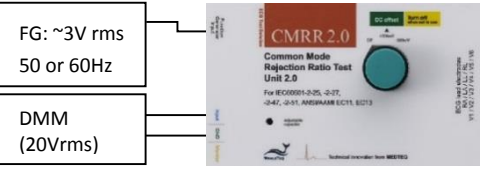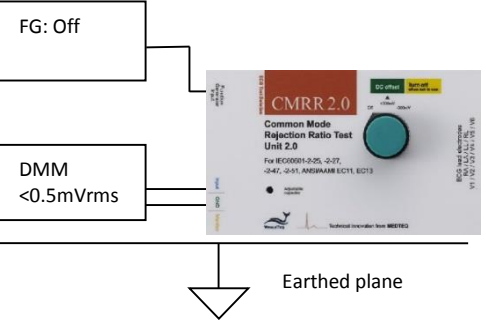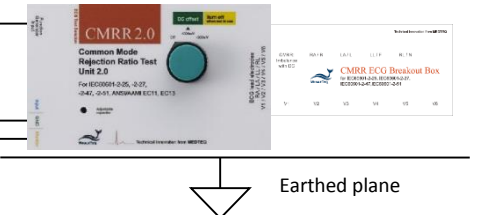
DC offset switch is accidentally left on continuously (e.g. while in storage), the battery will require replacement. Contact WhaleTeq for details if this occurs.

Test experience indicates that due to the right leg drive, there can be short period of 1-2s while the equipment "learns" the noise. This can result in transient response which can be ignored.

Earlier designs of WhaleTeq equipment incorporated the CMRR test circuit inside the USB module, but found that results were not the same as separate double box construction. The suspected reason is that the right leg drive is unable to respond correctly if there is other higher frequency noise around.
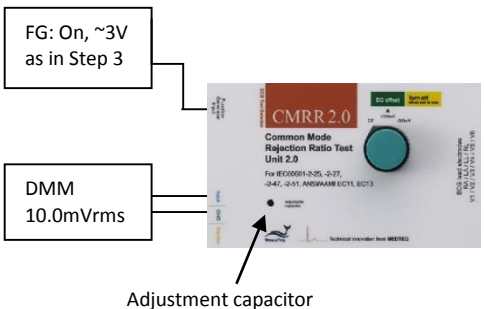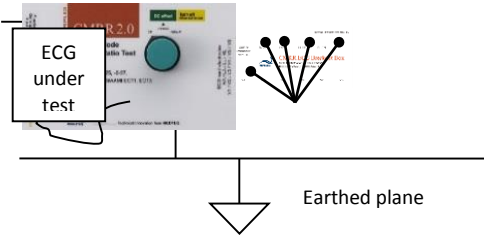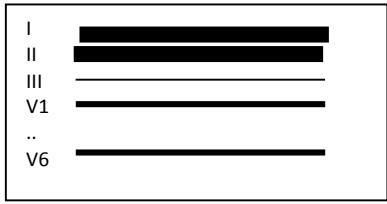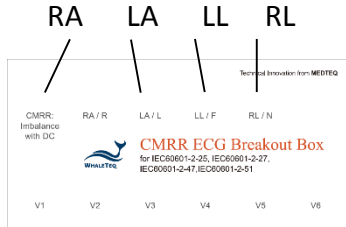
6   Operation

Operation will typically follow these steps:

Step	Procedure	Diagrams
1	Set up noise free environment as described in Section 3.	
2	Connect a function generator to the BNC terminal. Alternate: if bypassing the transformer, a test supply (e.g. 20Vrms, 50 or 60Hz) can be connected directly to the "Input." In this case take care with the Warnings and Cautions given in Section 7.	
3	Turn on the source, and adjust to the desired voltage[2] (20Vrms), by monitoring the voltage between the "Input" to "GND."	
4	Using a battery operated digital multimeter with at least 0.1mV resolution, connect to the "Monitor" and "GND" terminals. Keep the leads and meter on the earthed plane. Verify that with the source off, the indication on the meter is <0.5mV. If not check adjust grounding, remove nearby noise sources or choose a different location. If more than 0.5mV remains, record as a potential source of error[3]. Some meters have the ability to filter out higher frequency noise (above 1kHz), use this feature if available.	
5	If the ECG breakout box is used, make sure this is connected and also above the earthed plane. Note: This is to fix the unloaded capacitance. The breakout box adds about 10pF load when sitting on an earthed plane.	

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[2] Use 20Vrms for IEC60601-2-27, IEC60601-2-51. Refer to the standard for IEC60601-2-47.

[3] In general even 1mVrms noise (equivalent to 1V) should not influence a pass/fail result. If the ECG equipment fails the test (indication >10mm) it may be necessary to reduce noise.

6	Turn on the supply. Using the "adjustment capacitor" adjust to 10mVrms (equivalent to 10Vrms) without the ECG device under test connected. The "adjustment capacitor" can be adjusted using a small screw driver. Note: If metal, insulate the portion of the handle of the screwdriver which will be touched with 2-3 turns of electrical tape, and adjust the voltage to around 3-5% lower than the target (e.g. 9.5 ~ 9.7mV). After removing the screwdriver, the voltage typically increases 3-5%. The adjustment uses a half plate capacitor without an end stop. Earlier units used 5-30pF; later units use 6-50pF.	FG: On, ~3V as in Step 3 DMM 10.0mVrms Adjustment capacitor	
7	Turn the source off, and connect the ECG to the set up (RA to RA, LA to LA etc), keeping the ECG leads above the earthed plane. With the source off, confirm indication on the ECG is less than 1mm peak to valley (peak to peak). This is a double check that the environment noise is sufficiently low.	ECG under test Earthed plane	ECG under test
8	Turn on the source, connect RA to the imbalance terminal and measure the indication on all leads (Lead I, II, III, V1 ~ V6). Note: With RA on the imbalance terminal, an indication is expected on Leads I, II, but not on lead III. Also a 1/3 indication on chest leads Vn is expected due the normal lead relation.	I II III V1 .. V6	
9	Repeat the test for all leads by swapping each lead to imbalance terminal in turn. Repeat the tests with +300mV and -300mV if required by the standard. Note: It is recommended to return each lead to their original position after each test to avoid confusion and tangled cables.	RA LA LL RL CMRR: Imbalance with DC RA / R LA / L LL / F RL / N CMRR ECG Breakout Box for IEC60601-2-25, IEC60601-2-27, IEC60601-2-47, IEC60601-2-51 V1 V2 V3 V4 V5 V6	
10	When complete, ensure the dc is set to off. This ensures the internal battery is not depleted.	DC offset Turn off when not in use Off +300mV -300mV	

7   Warnings/Cautions/Notes

Please consider the following warnings / cautions with this equipment:

1. Input other than function generator [WARNING]
    If the 20Vrms input is sourced directly (bypass the function generator input/transformer), take appropriate precautions. In particular:

    a. There is no input protection provided
    b. Do not apply more than 30Vrms
    c. Do not connect a function generator at the same time
    d. Use a safety isolation transformer (separation between the 20Vrms circuit and accessible parts is not designed for safety insulation).

2. Residual test set up noise [CAUTION]
    It is normal to have a small amount of residual noise (of up to 1mmpp) when no input is applied. It is not necessary to reduce this further provided the margin between the test result and the limit is greater than this noise. (e.g. noise = 1mm, limit = 10mm, test result = 6mm). In other cases, additional efforts should be made to reduce the noise (increase the metal shield around the test set up, make sure the operator is touching the shield during the test, or choose a different test location)

    If a function generator input is used and the frequency is different to that of the environment (e.g. input 50Hz, environment 60Hz) the result on the ECG may show some "beating" with the residual noise from the environment. This beating should be at a frequency equal to the *difference* in frequencies (e.g. 10Hz) and not greater in amplitude than the residual noise when no input is applied.

    If the set frequency is nominally the same as the environment (e.g. input 50Hz, environment 50Hz) the beating may be extremely slow because of slight differences in frequency (e.g. environment noise 50.00Hz, function generator 50.10Hz would result in beating with 10s period).

    The beating above is not of concern provided the margin to the limit is sufficient.

3. Battery life [CAUTION]

    The internal 300mV is sourced from a SR44 1.5V alkaline battery. By calculation this battery should last in excess of 100hrs, which far exceeds the expected demands during testing. However, if the user accidentally leaves the DC offset switch on the battery can be depleted and will require replacement. This in turn requires disassembly of equipment including the internal shield. Later models have made this easier to perform however it is best to avoid this situation by ensuring that the switch is off in normal use.

8   Specifications

Item	Additional Details (if required)	Specification	Design capability*
Input transformer	Step up to allow use with a function generator	Ratio not lower than 4:1 (e.g. drive voltage 5Vrms or less is required).	-
Voltage divider	1000:1 using 50MΩ:50kΩ	Ratio accuracy ±2%	±1%
Series capacitance	100pF	100pF ± 5%	±5%
Imbalance impedance, R	51kΩ	51kΩ ±1%	±0.5%
Imbalance impedance, C	47nF	47nF ± 5%	±5%
DC offset	Internal battery powered	300mV ± 1% Up to 50hrs with intermittent use	±0.3%
Environment	Intended for normal laboratory environment. The selection of critical components is known to be stable in the range shown. The 50MΩ divider may be affected by high humidity in excess of 85%.	15-30°C 10-75% RH	

* Assured by selection of components or adjustment.

9   Contact details

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